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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* GINO F. MORELLO

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Appeal 2015-005077  
Application 12/594,792  
Technology Center 3700

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Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and  
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

*PER CURIAM*

DECISION ON APPEAL<sup>1</sup>

This Appeal under 35 U.S.C. § 134(a) involves claims 1–20 (App. Br. 6–24). Examiner entered rejections under 35 U.S.C. §103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> Appellant identifies “Reliant Heart, Inc. [as] the real party in interest” (App. Br. 2).

## STATEMENT OF THE CASE

Appellant’s invention “relates generally to blood pump systems, and more particularly to blood pump systems and operation methods associated therewith” (Spec. ¶ 10). More particularly, Appellant’s systems include “an implantable flow measurement device” and a “processing device [that] receives indications of pump parameters” (*id.* at ¶ 17). Independent claims 1, 9, and 17 are representative and reproduced in the Claims Appendix of Appellant’s Appeal Brief.

Claims 1–3, 5, 8, and 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss<sup>2</sup> and Doten.<sup>3</sup>

Claims 6, 9–11, 13, 14, and 16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and Truitt.<sup>4</sup>

Claims 4, 18, and 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and Bainbridge.<sup>5</sup>

Claim 7 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and O’Mahony.<sup>6</sup>

Claim 12 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, Truitt, and Bainbridge.

Claim 15 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, Truitt, and O’Mahony.

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<sup>2</sup> Weiss et al., US 4,828,543, issued May 9, 1989.

<sup>3</sup> Doten et al., US 6,063,034, issued May 16, 2000.

<sup>4</sup> Truitt et al., US 5,910,252, issued June 8, 1999.

<sup>5</sup> Bainbridge et al., US 6,899,691 B2, issued May 31, 2005.

<sup>6</sup> O’Mahony et al., US 2005/0004502 A1, published Jan. 6, 2005.

Claim 20 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and Brugger.<sup>7</sup>

## ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

## FACTUAL FINDINGS (FF)

FF 1. Weiss suggests

A method and apparatus for extracorporeal circulation and treatment of blood. The apparatus comprises means for circulating and for treating blood, with a control system for controlling the circulating means. . . .

. . .

. . . Sensors measure pressures within the tubing, at the inlet and outlet of the filter. Fluid flow rate can be calculated from the speeds of the pumps.

The control system includes a central processor that receives input data from the sensors and the pumps to regulate the apparatus. The central processor will regulate the venous pump to maintain a specified outflow rate. . . . The central processor regulates the arterial pump speed as necessary to achieve the desired transmembrane pressure, while the venous pump rate is held steady.

(Weiss Abstract; *see also* Final Act. 2–4.)

FF 2. Weiss suggests that

[t]he control system may include a central processor having both communication hardware and operational hardware. The communication hardware transmits information between the central processor and a technician, or operator, operating the apparatus. The communication hardware may include display

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<sup>7</sup> Brugger et al., US 7,004,924 B1, issued Feb. 28, 2006.

equipment and an input device. The display equipment includes an electronic alphanumeric display that can both prompt the operator for input and display relevant operating parameters. The input device is a keypad by which the operator enters chosen values for variables that govern operation of the apparatus.

The operational hardware may include both monitoring devices and control devices. Monitoring devices may include sensors to measure pressures and/or flow rates of the fluid within the circulation means or the treatment means. The sensors include pressure sensors that measure fluid pressure substantially at the inlet and/or the outlet of the treatment means, as necessary. The sensors also include means to measure the flow rate of fluid upstream and/or downstream of the treatment means. Fluid flow rate can be measured directly, or by monitoring of the speeds of the arterial pump and/or the venous pump, thereby to provide for calculating fluid flow rates through the monitored pump.

The control devices may include means for regulating the flow into and out of the treatment means. Motor controllers provide direct speed regulation of the arterial pump and the venous pump.

The central processor receives input data and regulates the appropriate elements of the apparatus to achieve the desired results entered into the keypad. The operator inputs a desired outflow rate from the apparatus, and the central processor regulates the venous pump motor controller accordingly. The operator can vary the outflow rate at any time by entering a new outflow parameter into the keypad. The central processor will regulate the venous pump motor controller to achieve the newly specified outflow rate. . . . To adjust the calculated transmembrane pressure, the central processor signals the arterial motor controller to regulate the arterial pump speed as necessary while, again, the venous pump produces the specified outflow rate.

(Weiss 9:14–62; *see also* Final Act. 2–4.)

FF 3. Doten suggests

a method and apparatus for estimating blood flow or blood flow velocity in a blood vessel over a period of time. According to the method, at least part of the measurement circuits used to estimate blood flow are automatically activated only during the time an estimate is being obtained. At least part of the measurement circuits are automatically deactivated during the time an estimate is not being obtained. These steps are performed repeatedly to provide a sequence of blood flow estimates forming a blood flow waveform indicative of blood flow. More than one estimate is typically required to obtain a waveform representative of the blood flow.

(Dotten 1:53–64; *see also* Final Act. 2–5.)

#### ANALYSIS

*The combination of Weiss and Doten:*

*Claims 1 and 17*

Appellant’s independent claim 1, requires, *inter alia*,

a processing device receiving indications of pump parameters, the processing device being programmed to energize the flow measurement device, determine flow rate based on the pump parameters and compare the determined flow rate to the measured flow rate, power off the flow measurement device, and then utilize the determined flow rate to control the pump.

(*See* Appellant’s claim 1.) Independent claim 17 similarly requires, *inter alia*, “a processing device receiving indications of pump parameters, the processing device being programmed to – determine flow rate based on the pump parameters[,] selectively power the flow measurement device and extract a measured flow rate from the flow measurement, compare the determined flow rate to the measured flow rate” (*see* Appellant’s claim 17).

We adopt Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 2–8; Ans. 3–4; FF 1–6) and

agree that the claims are obvious over Weiss and Doten. Specifically, based on the combination of Weiss and Doten, Examiner concludes that, at the time Appellant's invention was made, it would have been *prima facie* obvious to "modify Weiss to include powering off the flow measurement device such as that taught by Doten in order to save power while the pump is in operation" (Final Act. 3; *see also* Final Act. 3, 5).

We recognize, but are not persuaded by Appellant's contention that "Weiss says nothing about 'compar[ing] the determined flow rate to the measured flow rate, power[ing] off the flow measurement device, and then utiliz[ing] the determined flow rate to control the pump.'" (App. Br. 8). Appellant further argues that "the undersigned has found no suggestion in Doten of 'determin[ing] flow rate based on the pump parameters and compar[ing] the determined flow rate to the measured flow rate, power[ing] off the flow measurement device, and then utiliz[ing] the determined flow rate to control the pump', as claimed" and that "Doten does not appear to teach controlling a pump at all" (App. Br. 9; *see also* App. Br. 10).

As Examiner explains,

it is clear from the Abstract of Weiss that his device comprises a central processing unit that maintains a determined flow rate by measuring a current flow rate, linked to pressures measured within the device, and altering the pump parameters accordingly to maintain a determined flow rate. The Examiner would like to stress that Doten is only relied upon to teach that a flow meter can be turned on or off, or strobed as Doten described, which the Appellant admits is taught by Doten.

(Ans. 3; FF 1–3; *see also* App. Br. 9 ("Doten does appear to teach powering a flow meter on and off, and does so for much the same reason as does the present invention").) Moreover, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the

teachings of a combination of references []. [The reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Appellant contends that “the Examiner does not address the ‘compar[ing] the determined flow rate to the measured flow rate’ language” (App. Br. 8; *see also* Reply Br. 4–5). Appellant argues that “what the cited portion of Weiss actually teaches is comparing two calculated, or determined, flow rates, not a determined flow rate to a measured flow rate, as those terms are used in the claims” (App. Br. 13).

These arguments are unpersuasive. Weiss suggests that “[s]ensors measure pressures within the tubing, at the inlet and outlet of the filter. Fluid flow rate can be calculated from the speeds of the pumps” (FF 1). Weiss also suggests

[t]he operational hardware may include both *monitoring devices and control devices*. Monitoring devices may include *sensors to measure pressures and/or flow rates* of the fluid within the circulation means or the treatment means. The sensors include pressure sensors that measure fluid pressure substantially at the inlet and/or the outlet of the treatment means, as necessary. *The sensors also include means to measure the flow rate of fluid upstream and/or downstream of the treatment means. Fluid flow rate can be measured directly, or by monitoring of the speeds of the arterial pump and/or the venous pump, thereby to provide for calculating fluid flow rates through the monitored pump.*

The control devices may include means for *regulating* the flow into and out of the treatment means. Motor controllers provide direct speed *regulation* of the arterial pump and the venous pump. The central processor receives input data and *regulates* the appropriate elements of the apparatus *to achieve the desired results* entered into the keypad. The operator inputs a desired outflow rate from the apparatus, and the central processor *regulates* the venous pump motor controller accordingly. The

operator can vary the outflow rate at any time by entering a new outflow parameter into the keypad. The central processor will *regulate* the venous pump motor controller to achieve the newly specified outflow rate. . . . To adjust the calculated transmembrane pressure, the central processor signals the arterial motor controller to *regulate* the arterial pump speed as necessary while, again, the venous pump produces the specified outflow rate.

(FF 2 (emphasis added).) Weiss uses sensors to measure pressure and to calculate fluid flow rate from pump speed (FF 1); uses monitoring and control devices in which sensors measure the flow rates, i.e., fluid flow rates are measured directly or determined indirectly; and regulate flow, pump speed and appropriate elements to achieve the desired results (FF 2). Therefore, Weiss necessarily compares determined flow rate to the measured flow rate. Identical language between the prior art and claims is not required to sustain a prior-art rejection. *In re Skoner*, 517 F.2d 947, 950 (CCPA 1975) (“Any other result would permit the allowance of claims drawn to unpatentable subject matter merely through the employment of descriptive language not chosen by the prior art.”)

Appellant argues that “the Examiner attempts to bridge the gap by citing Doten, and alleging ‘Doten discloses a blood flow meter wherein the flow measurement device is energized and then powered off while using the determined flow rate to control the pump’. **This is simply not true**” (App. Br. 9).

We are not persuaded. Doten suggests

at least part of the measurement circuits used to *estimate blood flow are automatically activated only during the time an estimate is being obtained. At least part of the measurement circuits are automatically deactivated during the time an estimate is not being obtained.* These steps are performed repeatedly to provide

a sequence of blood flow estimates forming a blood flow waveform indicative of blood flow. More than one estimate is typically required to obtain a waveform representative of the blood flow.

(FF 3 (emphasis added).) Moreover, as Appellant admits, “Doten does appear to teach powering a flow meter on and off, and does so for much the same reason as does the present invention” (App. Br. 9).

*The combination of Weiss, Doten, and Truitt:*

#### FACTUAL FINDINGS (FF)

FF 4. Truitt suggests “the controller is further operative for correlating the selected flow rate with the stored flow rate and for adjusting the stored flow rate to effect treatment of the blood in accordance with the treatment and the flow rate selected” (Truitt 25:43–46; see also Final Act. 3–4).

#### ANALYSIS

##### *Claim 9*

Independent claim 9 similarly requires, *inter alia*, “energize the flow measurement device and measuring the flow rate of fluid being pumped; determining flow rate based on the pump parameters; comparing the determined flow rate to the measured flow rate” (*see* Appellant’s claim 9). Dependent claim 11 requires “periodically powering off the flow measurement device” (*see* Appellant’s claim 11).

We agree with Examiner that the claims are obvious over Weiss, Doten, and Truitt. Specifically, Examiner acknowledges that the combination of Weiss and Doten “does not [suggest] comparing the determined flow rate to the measured flow rate [periodically], powering on and off the measurement device periodically while controlling the pump[]

based on the determined flow rate, or accessing look-up tables to derive the determined flow rate” (Final Act. 3; *see also* Ans. 3). Examiner, therefore, turns to Truitt and finds that, with respect to, “Claims 9 and [11], Truitt discloses a method of operating a blood pump comprising periodically comparing the determined flow rate to the measured flow rate and altering the pump parameters to match the two values (claim 3)” (Final Act. 3–4; *see also* Ans. 3 (“the Examiner . . . incorrectly labelled the Truitt reference to apply to claims 9 and 10 instead of claims 9 and 11”)).

Therefore, based on the combination of Weiss, Doten, and Truitt, Examiner concludes that, at the time Appellant’s invention was made, it would have been *prima facie* obvious to “modify Weiss to include the comparison of the determined flow rate to the measured flow rate such as that taught by Truitt in order to confirm that the operation being performed on the patient was proceeding properly” and to “modify Weiss to include powering off the flow measurement device such as that taught by Doten in order to save power while the pump is in operation” (Final. Act. 4).

Appellant contends that “Weiss does not disclose comparing the determined flow rate to the measured flow rate, powering on and off the measurement device periodically while controlling the pumped based on the determined flow rate, or accessing look-up tables to derive the determined flow rate” (App. Br. 14; *see also* Reply Br. 7); “Doten does not teach determining a flow rate based on pump parameters, and therefore simply cannot teach or fairly suggest ‘comparing the determined flow rate to the measured flow rate and then powering off the flow measurement device while using the determined flow rate to control the pump[]’” (App. Br. 15); and, in regard to Truitt, “[t]he undersigned has found no discussion of

comparing a determined flow rate with a measured flow rate, as those terms are used in the claims” (*id.* at 16).

We are not persuaded for the reasons discussed above. *See also In re Merck & Co.*, 800 F.2d at 1097.

Appellant argues that “the Examiner asserts ‘Truitt discloses a method of operating a blood pump comprising periodically comparing the determined flow rate to the measured flow rate’, which is not true, ‘and altering the pump parameters to match the two values’, which appears irrelevant to claim 9, even if true” (*id.*).

We are not persuaded. As Examiner explains,

In regards to the Appellant’s arguments against the rejection of Claim 9, a misunderstanding caused by a typo/omission has caused confusion. As described above, Weiss is clear about comparing a measured flow rate against a determined flow rate and altering pump parameters accordingly. However, in the *Graham v. Deere* statements of obviousness, the Examiner omitted the word “periodically” in line 2 of the paragraph beginning “However, Weiss . . .” and incorrectly labelled the Truitt reference to apply to claims 9 and 10 instead of claims 9 and 11. Again, as above, the teachings of Weiss in regards to the functions of his central processing unit apply, and Doten is only relied upon to teach that in a blow flow measurement device the flow sensor can be strobed, or powered on and off.

(Ans. 4; FF 4.) Moreover, Appellant provides no persuasive argument or evidence other than contending that Examiner’s findings with respect to Truitt “is not true.” “Attorney’s argument in a brief cannot take the place of evidence.” *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

*The combination of Weiss, Doten, and Bainbridge:*

FACTUAL FINDINGS (FF)

FF 5. Bainbridge suggests that

separation device . . . will pause all pumps when the pressure reaches an alarm point. In the draw cycle, device . . . can then hold this pause until the pressure rises above the negative alarm point or another discrete set point (such as -50 mmHg, for example). An audible squeeze beep sound or other warning alarm signal, message or the like can be emitted by device . . . during this pump pause at least so long as the pressure remains below the alarm or other set point. Device . . . can further set or have a set time limit (for a period of for example 6 seconds) for an automatic resolution during this pause after which, if there is no resolution, a regular/full alarm condition occurs. Resolution is the pressure rise to above the alarm or other pre-selected set point. The regular/full alarm condition involves complete stoppage of all pumps and requires operator intervention to re-start the pumps.

(Bainbridge 9:63–10:11; *see also* Final Act. 5.)

ANALYSIS

Claims 4 and 18 each requires “the flow measurement device is powered off for a time period determined in response to the difference between the determined flow rate and the measured flow rate,” and claim 19 requires “the period of time is based on a difference between the determined flow rate and the measured flow rate” (*see* Appellant’s claims 4, 18, and 19).

We agree with Examiner that the claims are obvious over Weiss, Doten, and Bainbridge. Specifically, Examiner acknowledges that “Weiss and Doten do not disclose powering off the flow measurement device for a set time period based off the difference in measured and determined flow rate” (Final Act. 5). Examiner, however, finds that “Bainbridge discloses a shutdown of blood pumps for a certain time period when a difference in

determined and measured pressure reaches an alarm point (Column 9 line 63 – Column 10 line 11)” (*id.*). Therefore, based on the combination of Weiss, Doten, and Bainbridge, Examiner concludes that, at the time Appellant’s invention was made, it would have been prima facie obvious to “include a shutdown for a given time period when a certain difference had been reached in the determined and measured pressure such as taught by Bainbridge since there would be no flow to measure when the blood pumps were deactivated” (*id.*).

Appellant contends that

the Examiner does not assert that Bainbridge teaches anything regarding flow. More specifically, the Examiner does not assert that Bainbridge teaches powering off a flow meter, much less doing so **for a period of time** that is determined or based on a difference in measured flow and determined flow. There is a difference in shutting down pumps “**when** a difference in determined and measured pressure reaches an alarm point”, emphasis added, as Bainbridge is alleged to teach, and powering off a flow measurement device “**for a time period** determined in response to the difference between the determined flow rate and the measured flow rate”, as actually claimed. Thus, even accepting the Examiner's characterization of Bainbridge, the Examiner’s amalgamation of references still does not teach the claim limitations.

(App. Br. 18–19; *see also* Reply Br. 8–9.)

These arguments are unpersuasive. As Examiner explains,

Bainbridge is only relied upon for the alarm conditions, in that there are certain thresholds relied upon to cause a shut off of the meter - described as a shutdown of the whole system. Doten teaches the process of turning on and off the meter, and in combination with the alarm limits of Bainbridge, discloses the limitations of claims 4, 12, and 18–19.

(Ans. 4; FF 3, 5.) *See also In re Merck & Co.*, 800 F.2d at 1097.

*The combination of Weiss, Doten, and O'Mahony:*

Appellant presents no additional argument based on the teachings of O'Mahony, and rely on the same arguments addressed above. For the reasons discussed above, therefore, we affirm the rejection of claim 7.

*The combination of Weiss, Doten, Truitt, and Bainbridge:*

Appellant similarly argues that

there is a difference in shutting down pumps “**when** a difference in determined and measured pressure reaches an alarm point”, emphasis added, as Bainbridge is alleged to teach, and powering off a flow measurement device “**for a time period** determined in response to the difference between the determined flow rate and the measured flow rate”, as actually claimed. Bainbridge's time periods are fixed, or completely undefined, and are not determined in response to any comparison, much less a comparison of a measured flow to a determined flow. Even the Examiner's stated reason for combining Weiss, Doten, and Bainbridge is illogical.

(App. Br. 22.)

We are not persuaded for the reasons discussed above.

*The combination of Weiss, Doten, Truitt, and O'Mahony:*

Appellant presents no additional argument based on the teachings of O'Mahony, and rely on the same arguments addressed above. For the reasons discussed above, therefore, we affirm the rejection of claim 15.

*The combination of Weiss, Doten, Truitt, and Brugger:*

FACTUAL FINDINGS (FF)

FF 6. Brugger suggests that

[t]he ultrasonic or other non-contact flow measuring device is preferably mounted over an exterior surface of a blood return line to the patient, more preferably being close to the blood return site on the patient so that the blood is monitored immediately prior to its return to the patient. Use of the ultrasonic flow sensing device also permits the detection of entrained air or other gases in the blood since the ultrasonic signal generated by air passing through the sensor will be immediately detectable i.e. the air will disrupt reflectance of the ultrasound signal which can be readily detected.

(Brugger 3:44–53; *see also* Final Act. 7.)

ANALYSIS

Claim 20 requires “a difference between the determined flow rate and the measured flow rate is used it indicate an abnormality in a flow path of the pump” (*see* Appellant’s claim 20).

We agree with Examiner that claim 20 is obvious over Weiss, Doten, Truitt, and Brugger. Specifically, Examiner acknowledges that “Weiss and Doten do not disclose that a difference between the determined flow rate and the measured flow rate is used to indicate an abnormality in a flow path of the pump” (Final Act. 7). Examiner finds, however, that “Brugger discloses a blood pump wherein a difference between the determined flow rate and the measured flow rate is used to indicate an abnormality in a flow path of the pump (Col 3 Ln 44–53)” (*id.*). Therefore, based on the combination of Weiss, Doten, Truitt, and Brugger, Examiner concludes that, at the time Appellant’s invention was made, it would have been obvious to “modify

Weiss and Doten to include the abnormality detection such as that taught by Brugger in order to anticipate a pump blockage” (*id.* at 8).

Appellant contends that “the cited portion of Brugger merely talks about detecting an anomaly using an ultrasonic flow measuring device. This does not speak to using ‘a difference between the determined flow rate and the measured flow rate [to] indicate an abnormality in a flow path of the pump’, as claimed” (App. Br. 24; *see also* Reply Br. 10).

This argument is unpersuasive. As Examiner explains, “Brugger discloses in the cited section that the ultrasonic measurement device is a flow measurement device with the added benefit of detecting abnormalities. Therefore, Brugger in practice would determine a change in flow and associate that with an abnormality in the flow path” (Ans. 4; FF 6). *See also In re Merck & Co.*, 800 F.2d at 1097. *See also In re Pearson*, 494 F.2d at 1405.

#### CONCLUSION OF LAW

The preponderance of the evidence relied upon by Examiner supports a conclusion of obviousness.

The rejection of claims 1 and 17 under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss and Doten is affirmed. Because they were not separately argued, claims 2, 3, 5, and 8 fall with claim 1.

The rejection of claims 6, 9–11, 13, 14, and 16 under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and Truitt is affirmed.

The rejection of claims 4, 18, and 19 under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and Bainbridge is affirmed.

The rejection of claim 7 under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and O'Mahony is affirmed.

The rejection of claim 12 under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, Truitt, and Bainbridge is affirmed.

The rejection of claim 15 under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, Truitt, and O'Mahony is affirmed.

The rejection of claim 20 under 35 U.S.C. § 103(a) as unpatentable over the combination of Weiss, Doten, and Brugger is affirmed.

#### TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED